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10/672,229	09/26/2003	Vinod Sharma	P-11083.00	2880

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3766	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,229	SHARMA, VINOD	
	Examiner	Art Unit	
	Frances P. Oropeza	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/5/06 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement

1. Ms. Nicole Kramer was the Examiner originally assigned to this case. Ms. Kramer is no longer an employee of the U.S. Patent and Trademark Office. Since this case was in mid-prosecution at the time of Ms. Kramer's departure, it has been assigned to a new Examiner. The current Examiner acknowledges the Applicant's response of 12/5/06, and provides responses to the arguments below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 8, 19- 23 and 25- 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, line 2 and claim 22 ,lines 2-3, "the pre-ATP rate" lacks antecedent basis.

In claim 4, line 5 and claim 22, line 5, "the post-ATP rate" lacks antecedent basis.

In claim 8, line 5 and claim 30, lines 3-4, "the ATP cycle length" lacks antecedent basis.

In claim 8, line 5 and claim 30, line 4, "the number of ATP pulses" lacks antecedent basis.

In claim 19, line 5, it appears "further" should be deleted.

In claim 35, the final two words of the claim, "the database" lack antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. Claims 1-19, 20-23 and 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,167,308 ("DeGroot") in view of U.S. Patent No. 6,400,986 ("Sun et al.").

DeGroot discloses a method of delivering ATP regimens comprising:

(a) upon detection of a tachycardia episode, delivering an exploratory ATP sequence of pacing pulses to the heart chamber to elicit a paced depolarization of the heart chamber upon delivery of at least the last delivered ATP pulse (see, for example, col. 2, lines 46-61 in which two series of short series of ATP pulses are delivered);

(b) measuring an exploratory return cycle length (RCL) from the last delivered exploratory ATP sequence pacing pulse to the next detected intrinsic depolarization (after delivery of the second series of pulses, the IMD measures the return cycle T4 as described at col. 2, lines 61-63);

(c) formulating an ATP regimen having ATP cycle length parameters, wherein the cycle length is formulated as a function of the measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66. Since the applied inter-pulse interval varies depending upon whether the measured return cycle T4 increases or does not increase with respect to T3, the

ATP cycle length is considered to be "formulated as a function of the measured exploratory RCL"); and

(d) delivering the ATP regimen to the heart chamber.

With respect to claim 19, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

With respect to claims 2, 13, 9-21, 33 and 35, DeGroot teaches formulating an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66). In the method disclosed in DeGroot, if the return cycle T4 increases in comparison to return cycle T3, the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia. However, if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). DeGroot fails to teach that the next available

therapy may be selected based upon previously successful ATP regimens that successfully terminated a tachycardia when similar return cycles were calculated. Sun et al. teaches an IMD with ATP capability that is programmed to deliver ATP therapy upon detection of a tachycardia by employing a pacing regimen selected from a library, or database, of previously successful or unsuccessful pacing protocols (see col. 2, lines 20-53). The recorded protocols include the exploratory RCL, as the exploratory RCL is a parameter of the pacing protocol (see col. 2, lines 20-26; col. 3, lines 14-36; col. 5 @ 61-67). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select the next available therapy based upon previously successful ATP regimens that successfully terminated a tachycardia as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible by selecting a pacing regimen that successfully terminated a tachycardia when similar return cycles were calculated.

With respect to claims 3, 21, 25, and 36, Sun et al. teaches the use of success/failure counters associated with each pacing protocol contained in the library. After each attempt of ATP therapy using a particular protocol, the relevant counter is incremented to indicate the success or failure of the protocol in terminating the arrhythmia (see, for example, col. 2, lines 54-59).

With respect to claims 4-7, 15-16, 22, 26-29, and 37-38, DeGroot detects whether a tachycardia is occurring (see, for example, step 200 of Fig. 4a) and also detects whether the tachycardia terminates in response to delivered ATP pacing

therapy (see col. 5, lines 55-60). Detection of whether the tachycardia has terminated includes determining a post-ATP rate (see col. 5, lines 55-60). Although not explicitly stated, DeGroot utilizes a pre-ATP rate to detect whether a tachycardia episode is occurring (in the alternative, Applicant admits that it is known for a ICD to employ tachycardia classification algorithms that utilize detected heart rates in order to detect a tachycardia; see Applicant's specification at page 2. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the IMD of DeGroot to detect the pre-ATP rate in order to detect a tachycardia as is well known in the art in order to accurately detect a tachycardia condition). If the post-tachycardia rate is still determined to be a tachycardia but is different from the pre-ATP rate (i.e., if the tachycardia rate is decelerating, the same, or accelerating), it would have been obvious to one having ordinary skill at the time of applicant's invention to modify the combined IMD of DeGroot and Sun et al. to record in the result table/database whether the unsuccessful pacing regimen resulted in accelerating or non-accelerating tachycardia rate in order to provide a physician with more information regarding the effect of a particular pacing regimen on the patient's tachycardia condition. Further, if the tachycardia condition is deemed to be accelerating, it is known in the art that a cardioversion or defibrillation may be required (see, for example, U.S. Patent No. 4,998,974 to Aker).

With respect to claims 8-10, 18, and 30-32, DeGroot discloses that if the return cycle T4 increases in comparison to return cycle T3, the IMD increases the number of ATP pulses delivered (the IMD continues to deliver pacing pulses at the same pacing

interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia). In addition, DeGroot discloses that if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). The new pacing regimen may include reducing the inter-pulse pacing interval (see col. 6, lines 20-25).

With respect to claims 11-12, 14, 17, 23, and 34, Sun et al. teaches that the information contained in the success/failure counters may be used to calculate a success/failure ratio (see, for example col. 2, lines 59-63 and col. 6, lines 1-37). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select a therapy having the highest stored efficacy as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible.

With respect to claims 19-38, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot and or Sun et al. (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

The Applicant's arguments filed 12/5/06 have been fully considered, but they are not convincing.

The Applicant asserts that DeGroot does not teach or suggest storing either a measured RCL or a success rate of the delivered ATP therapy. The Examiner agrees. As noted in the rejection of record, the Sun et al. reference was included in the rejection to teach among other things, storing a measured RCL and storing a success rate of the delivered ATP therapy.

The Applicant asserts that Sun et al. do not teach measuring an exploratory RCL and storing a successful ATP regimen in association with the exploratory RCL. The Examiner agrees that Sun et al. do not teach measuring an exploratory RCL. In the rejection of record, measuring an exploratory RCL is taught by DeGroot. The Examiner respectfully disagrees that Sun et al. does not teach storing a successful ATP regimen in association with the exploratory RCL. Sun et al. does teach storing a successful ATP regimen in association with the exploratory RCL. A successful ATP regimen is stored (abstract). The exploratory RCL is associated with the successful ATP regimen, as the exploratory RCL is a parameter associated with the ATP regimen. The protocols in Sun et al. are read to include the exploratory RCL, as the exploratory RCL is a parameter of the pacing protocol (see col. 2, lines 20-26; col. 3, lines 14-36; col. 5 @ 61-67). It appears the word associated is causing confusion. In paragraph 13 of the instant specification, it is made clear the exploratory RCL is not only correlated or associated with the ATP regimen, but the exploratory RCL is also stored. If the intent of the Applicant is understood, it appears the phrase "storing the delivered ATP regimen as a

successful ATP regimen in association with the exploratory RCL measured in step (b) in IMD memory." could be changed to --storing the delivered ATP regimen and the associated exploratory RCL measured in step (e) as a successful ATP regimen in the IMD memory." The phrase including the word association is also found in at least claims 1, 3, 4, 6, 13, 15, 17, 19, 22, 25, 33 and 35-37.

Based on the discussion above, the rejection of record stands.

Specification

5. The instant specification is object to because:

- in paragraph 0036 reference numeral 100 is not found in the figures.
- in paragraph 0039 reference numeral 120 is not found in the figures.
- in paragraph 0042 reference numeral 166 is not found in the figures.
- in paragraph 0082 reference numerals step 340 and step 360 are not found in the figures.
- in paragraph 0084 reference numeral step 324 and step 326 are not
- found in the figures.
- in paragraph 0085 reference numeral step 322 and step 348 are not found in the figures.
- in paragraph 0085 reference numeral step 348 is not found in the figures.
- in paragraph 0088 reference numeral S362 is not found in the figure 4B.

Appropriate correction is required.

Drawings

6. The figures are objected to because:

- in figure 2, reference numerals 116 and 20 are not found in the instant specification.
- In figure 4A, reference numeral S328 is not found in the instant specification.
- in figure 4B2, reference numeral s382 is not found in the instant specification.

A proper drawing correction or corrected drawing is required in reply to this Office action to avoid abandonment of the application. The correction to the drawing will not be held in abeyance.

Oath

7. It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Carl H. Layno can be reached on (571) 272-4949. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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